

Resources for Provider-Performed Microscopy Sites

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Outline

- ❑ **Purpose for CLIAC Discussion**
- ❑ **PPM Background and CLIA Requirements**
- ❑ **CMS Surveys of Waived and PPM Laboratories**
- ❑ **Current PPM Laboratory Status and CLIAC Questions**

Purpose for CLIAC Discussion

- ❑ **Inquiries and comments suggest a need for educational resources for sites that test under a CLIA Certificate of Provider-performed Microscopy (PPM)**
- ❑ **Questions for CLIAC Consideration:**
 - Are you aware of knowledge gaps or misperceptions regarding CLIA among providers who perform PPM testing?
 - Would educational resources be helpful in filling such gaps?
 - If so, what types of materials would be most useful and what content should be included?



PPM BACKGROUND AND CLIA REQUIREMENTS

PPM History

- ❑ **January 1993 - Physician-performed microscopy was established as a CLIA certificate type and subcategory of moderate complexity testing**
 - Allowed physicians to perform certain microscopic examinations in addition to waived tests during the course of a patient's visit
 - Examinations categorized as moderate complexity
 - Limited to bright-field or phase-contrast microscopy
 - Specimens labile or testing delay could compromise accuracy of results
 - Limited specimen handling or processing required
 - Control (or proficiency testing) materials not available to monitor the entire testing process
 - Not subject to routine inspections but a CLIA certificate is required and must meet other quality standards

PPM History (cont.)

- ❑ **April 1995 – The subcategory was renamed provider-performed microscopy to include other practitioners and add to/clarify the tests that can be performed**
 - Midlevel practitioners - licensed (if state-required) nurse midwife, nurse practitioner, or physician assistant may test under physician supervision or independently if authorized by the state
 - Dentists may qualify as PPM directors or testing personnel
 - Changes to tests included
 - Clarification of wet mount examinations
 - Addition of three tests

PPM Procedures

- ❑ All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ❑ All potassium hydroxide (KOH) preparations
- ❑ Pinworm examinations
- ❑ Fern tests
- ❑ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ❑ Urine sediment examinations
- ❑ Nasal smears for granulocytes
- ❑ Fecal leukocyte examinations
- ❑ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)



CMS SURVEYS OF WAIVED AND PPM LABORATORIES

Initial Surveys

- ❑ **1999 pilot studies in Colorado and Ohio, as well as a 2001 report published by the HHS Office of Inspector General (OIG), indicated vulnerabilities in sites that perform waived testing and PPM procedures**
- ❑ **OIG recommended:**
 - Providing educational outreach to lab directors of waived and PPM labs
 - Requiring laboratories applying for waived and PPM certificates to identify which test systems they will use
 - Using periodic paper self-assessment tools to help ensure compliance for laboratories that are not routinely visited

Additional CMS Surveys of PPM Laboratories

- ❑ As part of the expanded CMS survey of waived and PPM laboratories, in 2000-2001 state agencies surveyed 190 sites performing PPM procedures in eight states**
 - Physician office laboratories - 71%
 - Nursing facilities - 13%
 - Community clinics - 5%
- ❑ Included some sites in states with licensing requirements**
- ❑ Observed quality problems that CMS would not have discovered without visiting**

CMS Findings for PPM Laboratories

- ❑ 25% of PPM laboratories did not document personnel competency**
- ❑ 38% do not evaluate test accuracy at least twice yearly**
- ❑ 6% have inappropriate certificates**
- ❑ States with licensure programs had five times fewer quality assurance problems than states without required licensure**
- ❑ Lack of routine external oversight (CMS survey or state licensure programs) of laboratories was found to be a significant challenge to ensuring quality**

CMS Recommendations Following the Waived/PPM Study

- ❑ Institute an educational program for waived and PPM laboratories and validate its effectiveness**
- ❑ Survey a percentage of waived and PPM laboratories annually**
- ❑ Develop a self-assessment tool for PPM laboratories**
- ❑ Provide educational material as part of the CLIA enrollment process**
- ❑ Have State Agencies contact waived and PPM laboratories to verify test menus**

- ❖ CMS now provides educational surveys in 2% of waived laboratories and verifies test menus in those sites, no specific actions taken to date for PPM laboratories**



CURRENT PPM LABORATORY STATUS AND CLIAC QUESTIONS

Status of PPM Certificate Laboratories*

- ❑ **PPM laboratories constitute 16.5% of the 234,104 CLIA-certified laboratories**
- ❑ **Physician office laboratories constitute 79% of PPM Certificates**
- ❑ **Remaining 21% of PPM Certificates include:**
 - Community clinics
 - School/student health services
 - Hospitals
 - HMOs
 - Ambulatory surgery centers
 - Other testing sites

Recent Questions and Observations Regarding PPM Procedures

- ❑ Development and distribution of educational materials promoting good laboratory practices for waived testing has generated interest in the need for similar materials for PPM procedures**
- ❑ Email inquiries received through CDC's waived testing mailbox have addressed:**
 - Requirements and process to obtain a PPM Certificate
 - Differentiation of waived and PPM Certificates
 - Testing permitted under PPM
 - Personnel training and qualification requirements for PPM
 - Requirements for proficiency testing for PPM procedures

Recent PPM Observations (cont.)

- ❑ **CMS surveyors and others who have received CDC materials on good laboratory practices for waived testing have suggested development of the following for PPM:**
 - Booklet(s) describing which tests are considered PPM, how to obtain a CLIA Certificate, and the regulatory requirements for performing PPM procedures
 - “Tips and Tools” document for PPM laboratories
 - Self-assessment tool for PPM laboratories

Questions for CLIAC Consideration

- ❑ Are you aware of knowledge gaps or misperceptions regarding CLIA among providers who perform PPM testing?
- ❑ Would educational resources be helpful in filling such gaps?
- ❑ If so, what types of materials would be most useful and what content should be included?



The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.